REMARKS

Claims 2-39 are presently pending in the case. Claims 2, 5, 7, 11, 14 and 16 have been amended. Claims 26-39 have been added. The amendments and new claims are supported by the specification and claims as originally filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 2, 5-7, 9-11, 14-26 (sic), 18-20 and 23 under 35 USC §103(a) as being unpatentable over U.S. Patent 5,522,383 to Calvert et al (hereinafter Calvert et al) in view of U.S. Patent 4,022,224 to Saifer et al (hereinafter Saifer et al). The rejection is traversed.

Calvert et al and Saifer et al do not render independent claim 2, for example, unpatentable under 35 U.S.C. 103(a). Claim 2 is to an apparatus comprising, inter alia, a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide, and a chamber wherein inlets are oriented so that gas may flow in a vortical flow path in the chamber and wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through a mouthpiece. It would not have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Calvert et al and Saifer et al in a manner that would arrive at the invention of claim 2 as will be described, and Calvert et al and Saifer et al therefore fail to render claim 2 unpatentable under 35 U.S.C. 103(a).

There is no prima facie case under 35 U.S.C. §103(a) established by the Examiner. The Examiner posits that Calvert et al teaches a powder inhaler and that Saifer et al teaches a powder protein (orgotein). The Examiner goes on to contend that

one of ordinary skill in the art at the time the invention was made would have found it obvious to substitute the Saifer et al powder protein for the powder delivered in the Calvert et al device. However, the Examiner's proposed modification fails to render claim 2 unpatentable.

Even assuming the teachings of Calvert et al and Saifer et al are combinable (which they are not, as discussed below), the system that would result from the proposed modification would not meet all the limitations of claim 2. For example, claim 2 recites "wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece." Nowhere in either reference is this amount of suspension discussed. In reference to this limitation, the Examiner points to column 4 lines 35-55 of Calvert et al, but a close reading of this section of the reference reveals nothing more than a teaching that a high degree of emptying is desirable. There is no mention of the degree of aerosolization that is achieved in Calvert et al. In addition, Calvert et al refers to a degree of emptying which is not the same as a percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece. Furthermore, all powders behave differently. A change in active agents within a powder will cause a change in powder characteristics. This change is likely to even be more exacerbated when going from a non-protein active agent to a protein active agent. Accordingly, the Examiner's apparent contention that by merely substituting the protein powder taught by Saifer et al for the powder used in Calvert et al would necessarily result in a system that meets the limitations of claim 2 is entirely without basis and is purely speculative. Since all limitations of claim 2 are not met by the proposed combination of references, the Examiner has failed to establish a prima facie case under 35 U.S.C. 103(a), and claim 2 is not rendered unpatentable by the references.

Furthermore, the teachings of Calvert et al and Saifer et al are not properly combinable under 35 U.S.C. 103(a) in that there is no teaching, suggestion, or motivation to combine the teachings of the references. There is nothing within the references to suggest to a person of ordinary skill in the art that combining the

teachings of the references would be desirable. In actuality, the opposite is the case, and one of ordinary skill in the art would be steered away from the proposed combination when the person of ordinary skill in the art considers the teachings of the references as a whole. For example, in the examples given by Saifer et al in columns 5 and 6, no example utilizes a powder inhaler formulation of the protein powder. Instead, all examples suggest using only a nebulized or pressurized aerosol type of formulation (see column 5 line 47-48). The dry powder preparation of Preparation 3 is ignored in the examples. Accordingly, one of ordinary skill in the art after considering the teachings of Saifer et al as a whole, would not have been motivated to use the Saifer et al teachings in a dry powder inhaler in place of the exemplified versions of Saifer et al. Moreover, it would not have then been obvious to select the Calvert et al device out of the numerous dry powder inhalers that were known at the time. The proposed combination is therefore additionally based entirely on impermissible hindsight reasoning and is not based on suggestions and motivations provided by the references themselves. Still further, there is no reasonable likelihood of success considering that Saifer et al fails to show that its dry powder is dispersible.

In addition to there being no teaching, suggestion, or motivation to combine Calvert et al and Saifer et al, the proposed modification is not one that is well within the grasp of a person having ordinary skill in the art. First, the Examiner has not demonstrated that there was a known problem for which there was an obvious solution encompassed by the claims. To the contrary, the teachings of the references give no indication that there was a problem associated with either teaching. It is not permissible to use the Applicant's disclosure of a problem as a motivation to provide a solution. Second, this is not a situation where it would have been "obvious to try." In order for an "obvious to try" rejection to be proper, it must be shown that there is a design need or market pressure to solve a problem and that there are a finite number of identified, predictable solutions. KSR v. Teleflex, 127 S. Ct. 1727 (2007). The Examiner has provided neither in the present case. There was no known design need or market pressure to solve a problem that would have been overcome by the proposed combination. Also, given the number of dry powder inhalers that were known and given

the limitless formulation choices available, there was not a finite number of identified, predictable solutions available. Accordingly, this is not a situation where a person having ordinary skill in the art at the time the invention was made would have seen the benefit of combining the references in the proposed manner.

Finally, secondary considerations dislodge any determination that claim 2 might have been obvious. The ability to deliver high value medicaments such as proteins and polypeptides efficiently and effectively is both novel and unexpected, as discussed in the present specification on pages 1-4. These unexpected results are but an example of secondary considerations that demonstrate the nonobviousness of claim 2.

For at least these reasons, claim 2 is not properly rejectable under 35 USC §103(a) as being unpatentable over Calvert et al and Saifer et al. In addition, claims 3-10 and 20-22 which depend from claim 2 are also not rendered unpatentable by Calvert et al and Saifer et al for at least the same reasons as claim 2.

Independent claim 11 is also not rendered unpatentable under 35 U.S.C. §103(a) by Calvert et al and Saifer et al. Claim 11 is to an apparatus comprising, inter alia, a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide and a chamber wherein inlets are oriented so that gas may flow in a vortical flow path in the chamber and wherein the volume of the aerosolized medicament is from 9.24 percent to 21.5 percent of the volume of the chamber. Calvert et al and Saifer et al do not teach this combination of features. Neither Calvert et al nor Saifer et al teaches a volume of aerosolized medicament that is from 9.24 percent to 21.5 percent of the volume of the chamber. The Examiner's contention that the claimed volume is "an obvious design consideration" (see page 3 of Final Office Action of September 7, 2007) is without basis. Even if it was obvious to combine the teachings of Calvert et al and Saifer et al (which it is not) and even if it was obvious to make "obvious design considerations" (which the Examiner has shown no reason to make), it is purely speculative that any such modification would result in a system that meets the limitations of claim 11. Accordingly, the Examiner has failed to

establish a prima facie case under 35 U.S.C. §103(a), and independent claim 11 is not properly rejected thereunder.

Additionally, it would not have been obvious to combine the teachings of Calvert et al and Saifer et al as proposed by the Examiner in a manner that would result in the invention of claim 11. First, as discussed above, there is no teaching, suggestion or motivation to combine the references as proposed. Secondly, also as discussed above, the proposed modification is not one that is well within the grasp of a person having ordinary skill in the art in that the Examiner has not demonstrated that there was a known problem for which there was an obvious solution encompassed by the claims. This is also not a situation where it would have been "obvious to try." Furthermore, secondary considerations dislodge any determination that claim 11 might have been obvious.

For at least these reasons, claim 11 is not properly rejectable under 35 USC §103(a) as being unpatentable over Calvert et al and Saifer et al. In addition, claims 12-19 and 23-25 which depend from claim 11 are also not rendered unpatentable by Calvert et al and Saifer et al for at least the same reasons as claim 11.

The Examiner rejected claims 3 and 12 under 35 USC §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of U.S. Patent 4,174,712 to Moren et al (hereinafter Moren et al). The rejection is traversed. Claims 3 and 12 depend from claims 2 and 11, respectively. Claims 2 and 11 are not rendered unpatentable by Calvert et al and Saifer et al as discussed above. Moren et al fails to make up for the deficiencies of Calvert et al and Saifer et al. Accordingly, claims 3 and 12 are allowable over Calvert et al, Saifer et al and Moren et al for at least the same reasons as claims 2 and 11.

The Examiner rejected claims 4, 8, 13 and 17 under 35 USC §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of U.S. Patent 3,809,084 to Hansen (hereinafter Hansen). The rejection is traversed. Claims 4 and 8

depend from independent claim 2, and claims 13 and 17 depend from independent claim 11. Claims 2 and 11 are not rendered unpatentable by Calvert et al and Saifer et al as discussed above. Hansen fails to make up for the deficiencies of Calvert et al and Saifer et al. Accordingly, claims 4, 8, 13 and 17 are allowable over Calvert et al, Saifer et al and Hansen for at least the same reasons as claims 2 and 11.

The Examiner rejected claims 21 and 24 under 35 USC §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of U.S. Patent 4,396,152 to Abplanalp (hereinafter Abplanalp). The rejection is traversed. Claims 21 and 24 depend from claims 2 and 11, respectively. Claims 2 and 11 are not rendered unpatentable by Calvert et al and Saifer et al as discussed above. Abplanalp fails to make up for the deficiencies of Calvert et al and Saifer et al. Accordingly, claims 21 and 24 are allowable over Calvert et al, Saifer et al and Abplanalp for at least the same reasons as claims 2 and 11.

The Examiner rejected claims 22 and 25 under 35 USC §103(a) as being unpatentable over Calvert et al and Saifer et al and further in view of U.S. Patent 4,860,740 to Kirk et al (hereinafter Kirk et al). The rejection is traversed. Claims 22 and 25 depend from claims 2 and 11, respectively. Claims 2 and 11 are not rendered unpatentable by Calvert et al and Saifer et al as discussed above. Kirk et al fails to make up for the deficiencies of Calvert et al and Saifer et al. Accordingly, claims 22 and 25 are allowable over Calvert et al, Saifer et al and Kirk et al for at least the same reasons as claims 2 and 11.

Claim Amendments

Claims 2, 5, 7, 11, 14 and 16 have been amended. All of these amendments have been made solely to correct typographical errors and have not been made for reasons related to patentability or to further limit the claims.

New Claims

Claims 26-39 have been added to define other aspects of Applicant's invention. The new claims are not intended as further limitations of previous claims and are not being added for reasons related to patentability.

Information Disclosure Statement

Applicant filed an information disclosure statement in compliance with MPEP section 609 on November 14, 2006. The Examiner erroneously lined-through several of the references stating in the Office Action of January 29, 2007 that the references failed to comply with 37 CFR 1.98(a)(2). The references listed were considered and indicated as such during the prosecution of the present case's parent case (see U.S. Patent 6,681,767 for example). Accordingly, the IDS of November 14, 2006 is in compliance with 37 CFR § 1.97 and 1.98, see MPEP §609.02. Applicant requests an indication of the consideration of the references.

Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: 31OCT2007

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